K101719

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510(k) SUMMARY
DALTON INSTRUMENT CORPORATION'S
Model TACAMO Manual Wheelchair

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

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3788 Arapaho Road
Addison, TX 75001
Tel: 469-522-1200
Fax: 469-522-1202

Contact Person:
President, Mei Lein
Date Prepared:
May 13, 2010

Name of Device and Name/Address of Sponsor

Model **TACAMO** Manual Wheelchair

Dalton Instrument Corp.
3788 Arapaho Road
Addison, TX 75001
Tel: 469-522-1200
Fax: 469-522-1202

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 89IOR

Predicate Devices

The Dalton Instrument Corp. Model **TACAMO** substantially equivalent to the Invacare Manual Wheelchair Model Action AT II **(K984447, 1/8/1999)** and Sunrise Medical/Quickie Design Model **"Quickie TSR"** Manual Wheelchair **(K952641, 6/9/1995)**

Intended Use: the intended use of the Model **TACAMO** Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

A. **Device Description**

The DALTON INSTRUMENT CORPORATION Model **TACAMO** is a manually operated, self propelled, manual, mechanical wheelchair. The primary design function and use is to provide mobility to persons who may be restricted to a sitting position. This product may also be used as an attendant propelled patient transport device in a health care environment such as a hospital, nursing home or long term care facilities.

The product has standard manual wheelchair features. It consists of the frame, 24" rear wheels with hand rims for propelling the chair, and 8" front casters for steering and turning.

The wheelchair frame is constructed from both 1.25" and 1" outside diameter(OD) round, mechanical, steel tubing. The side frames are of welded construction and are secured to the remaining frame members using screws and bolts. This device is a rigid, "non folding" type wheel chair that incorporates a solid seating surface. **TACAMO** also comes with wheelchair cushion and seating system.

TACAMO also includes a "Tilt in Space" feature which allows the seat and back of the wheelchair to be tilted. This feature is used for those patients who require a tilt feature for stability, comfort or head control. It also serves as an attendant aid in those situations where a patient need to be tilted to be fed, or attended to in some situations.

The "Tilt in Space" feature is manually operated and is activated by two release levers located at the rear of the wheelchair. Adjusting the tilt is achieved by squeezing the two release lever handles inward simultaneously. When the levers are squeezed, flexible cables attached to each release lever disengage gear rack segments from independent actuator rods which are notched to match the teeth of the gear segments. Once the desired tilt angle has been obtained, the handles are released and the chair will remain at the angle chosen. The chair has a tilt angle range of 30 degrees and 30 degrees of reclining angle.

B. **Substantial Equivalence**

The DALTON INSTRUMENT CORPORATION Model **TACAMO** substantially equivalent to numerous manual, mechanical wheelchairs currently in market place,

for which FDA has granted marketing clearance through the 510(k) premarket notification process. More specifically the DALTON INSTRUMENT CORPORATION Model **TACAMO** is substantially equivalent to the Sunrise Medical/Quickie Design Model **"Quickie TSR"** Manual Wheelchair**(K952641 6/9/95)** and the Invacare Model AT II Manual Wheelchair**(K984447 1/8/1999)**

Each of the products is a manual operated, attendant or user propelled, manual mechanical wheelchair with the same intended function and use which is to provide mobility to persons that may be limited to a seated position. All products consist basically of a mechanical frame to support the wheelchair, 24" rear wheels for propelling the wheelchair, and 8" casters for turning and steering. Additionally, each of these wheelchairs incorporates a manually operated "tilt in space" feature for patient comfort and positioning.

Performance Data

The DALTON INSTRUMENT CORPORATION wheelchair TACAMO meets the applicable performance requirements specified in:

- Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/Vol.1-1998 "Requirements and Test Methods for Wheelchairs(including Scooters)"

- DIS ISO 7176 (1992) – Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dalton Instrument Corporation
% Mei Lein
President
3788 Arapaho Road
Addison, Texas 75001

AUG 25 2010

Re: K101719
Trade/Device Name: TACAMO Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: August 9, 2010
Received: August 16, 2010

Dear Mei Lein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101719

Indications for Use

510(K) Number (if known): **K101719**

Device Name: **TACAMO Manual Wheelchair**

Indications for Use: The intended use of the TACAMO Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Prescription Use_____ AND/OR Over-The-Counter Use _X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101719